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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DAVIS, DEBORAH A	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,168	JACOBS ET AL.	
	Examiner	Art Unit	
	Deborah A. Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24,25 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24,25 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the Office Action mailed on March 3, 2006 has been acknowledged. Currently, claims 21-22, 25-25 are pending, which includes newly added claim 30. Claims 23, 26-29 are cancelled.

Claim Rejections - 35 USC § 103 are hereby maintained

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 21, 24-25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cusack et al (USP#5,302,348) in view of Michael D. Mintz (USP#4,551,308) and in further view of Shepherd et al (WO 94/08237).

The claims are broadly drawn to a method of determining the strength of an agglutination reaction within a hollow contain comprising walls capable of transmitting light at certain predetermined wavelengths. The reference of Cusack et al teaches an apparatus and method for performing a coagulation (agglutination) time test on a sample of blood (column 4, lines 23-28). Step (a) of the claim 21 provides a mixture of a sample within a first cavity of the container, said cavity having a first inside diameter. The reference teaches step (a) in that it teaches providing a blood sample that flows from a reservoir into a conduit (Figure 2, #30) which examiner interprets as the first cavity. Step (b) comprises

transferring the mixture to a second cavity having a second inside diameter substantially smaller than said first inside diameter. The reference teaches that the blood sample flows through the conduit, which is the first cavity, and then to the narrow region (Figure 2, #44) which examiner interprets as the second cavity having a second inside diameter substantially smaller than the first inside diameter. The conduit can comprise a clot specific surface that may be plasma treated or otherwise treated to provide more efficient clotting (column 6, lines 32-40). The reference of Cusak teaches that the blood sample present on either side of the conduit or the narrow, which is the second cavity region, can be detected by photoelectric sensors (column 8, lines 59-65). The light emissions from the light sources to the photoelectric sensors pass through the apparatus to the conduit, which contains the blood sample (column 8, lines 20-31), and therefore the sensors would detect light absorbed from the sample. Step (e) requires transferring the mixture back into said first cavity and step (f) requires steps (b) through (d) be repeated until some agglutinated material has separated from non-agglutinated material. The reference of Cusack et al anticipates steps (e) through (f) in describing a pneumatic pump that cycles the blood sample with the test conduit to reciprocally move from one side of the conduit to the other side of the restricted region and then back again. As the blood sample is cycled back and forth, the photoelectric sensors are used to count the time it takes for the blood to traverse the narrowed region and coagulate and clot (column 4, lines 58-68 and column 5, lines 1-2). Step (g) requires calculating the amount of agglutination from the absorbance or scattering detected said step (d). The

reference teaches when the traversed time of one cycle of travel is a predetermined a percentage longer than an immediately preceding cycle of travel, coagulation is considered to have occurred and the overall time for coagulation is displayed to the operator (column 5, lines 3-9). The examiner interprets this teaching as calculating the amount of agglutination from the absorbance in step (d) as required by step (g). The reference of Cusack et al teaches that as blood traverses back and forth through the narrowing region of the conduit and begins to coagulate and clot, it will occlude the normal flow of the blood sample through the narrowing region of the conduit. The examiner interprets this teaching as the separation of coagulated blood from non-coagulated blood.

The reference of Cusack et al is silent with respect to an agglutinating reagent.

However, the reference of Michael D. Mintz teaches an apparatus and method for analyzing the influence of coagulant and anticoagulant reagents in blood.

Cusack is silent with respect to the use of radiation at a certain predetermined 540 wavelength and detecting the amount of scattered radiation to avoid any hemolysis interference neither does it particularly point out scanning a 10% portion of the liquid sample at a predetermined wavelength.

However, Shepherd et al teaches a method and apparatus for direct spectrophotometric measurements, which allow accurate determinations of concentrations of various hemoglobin species in whole blood without hemolysis

or dilution. This apparatus designed to maximize the true optical absorbance of whole blood and to minimize the effects of light scattering on spectrophotometric measurements of concentrations of various constituent components and to correct the hemoglobin concentration measurements for light scattering and get true optical absorbance. Shepherd et al measured the hemoglobin in blood by selecting a quadruple wavelength in the range of 510-630nm, which minimized the error criterion in absorbance.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Cusack to include adding an agglutination reagent as taught by Mintz to determine the influence the reagent has on a patient's blood as in the time required to prolong the patient's coagulation time for therapeutic reasons. It would have been also obvious to modify Cusack to include the use predetermined wavelength as taught by Shepherd et al to scan blood samples which minimizes the error criterion in absorbance (page 5, lines 1-12). It would have been further obvious to one of ordinary skill in the art to modify the teaching of Cusack et al to include detecting the amount of scattered radiation to avoid any hemolysis interference as taught by Shepherd et al to get true absorbance values for hemoglobin and other components in the blood for detection. Especially since hemolysis of blood cells causes turbidity, which results in errors in hemoglobin measurements (page 5, lines 1-12). One would be motivated to detect scattered radiation to minimize errors in detection of blood. With respect to the limitation of scanning a 10% portion of the liquid closest to the first cavity of the invention, it is further obvious that is it within the skill of the artisan to scan

the portion of liquid for evaluation that gives the needed information sought after. Especially since it has long been held to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458, 105 USPQ at 236-237. The "discover of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Voesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cusack et al (USP#5302348) in view of Michael D. Mintz (USP#4,551,308) and in further view of Shepherd et al (WO 94/08237) as applied to claims 21, 24-25 and in further view of Zabetakis et al (USP#5773305).

Claim 22 is further drawn to a transfer step wherein the liquid moves down from the first cavity to the second cavity so that gravity will assist in the separation of step f). The reference of Zabetakis et al teaches method of diluting a fluid sample for analysis comprising a probe that has a first section with a first diameter and a and a second section having a diameter. The fluid sample and diluent are mixed in the second interior section of the probe by moving the sample and diluent back and forth in the second interior section a predetermined

number of times by alternate vacuum and pressure forces (gravity) applied to the fluid sample and diluent, (abstract and column 2, lines 1-29).

The reference of Zabetakis et al does not teach the scanning of the sample at predetermined wavelengths or an agglutinating reagent within the first cavity of the apparatus.

However, the reference of Cusack et al teaches a conduit that has been plasma treated to provide more efficient clotting (column 6, lines 32-40) which examiner interprets as an agglutination reagent. The reference of Cusack teaches an optical step wherein the blood sample present on either side of the conduit can be detected by photoelectric sensors (column 8, lines 59-65), which examiner interprets scanning the sample with a beam of light at predetermined wavelengths. The light emissions from the light sources to the photoelectric sensors pass through the apparatus to the conduit, which contains the blood sample (column 8, lines 20-31), and therefore the sensors would detect light absorbed from the sample. As the blood sample is cycled back and forth, the photoelectric sensors are used to count the time it takes for the blood to coagulate and clot (column 4, lines 58-68 and column 5, lines 1-2). The reference teaches when the traversed time of one cycle of travel is a predetermined a percentage longer than an immediately preceding cycle of travel, coagulation is considered to have occurred and the overall time for coagulation is displayed to the operator (column 5, lines 3-9). The examiner interprets this teaching as calculating the amount of agglutination from the absorbance in step (d) as required by step (g).

It would have been obvious to one of ordinary skill in the art to want to modify the reference of Zabetakis et al to include detecting agglutination of blood because because the reference of Cusack et al teaches that determining the coagulation time of blood which is necessary in order to stop both internal and external bleeding during surgical procedures (column 1, lines 1-26). One of ordinary skill in the art would want to be motivated to test agglutination of blood also to determine if there is any pre-existing disease that the patient may have that prohibits clotting before performing a surgical procedure. With respect to the second diameter being smaller than the first diameter, it is the position of the examiner that such a modification is an obvious matter of design choice and is generally recognized as being with the level of one skilled in the art

Response to Arguments

1. Applicant's arguments filed March 3, 2006 have been fully considered but they are not persuasive.

2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, although applicant argue that Cusack teaches

heparin and protomine which are anti-coagulants, Cusack also teaches a method for measuring ***blood coagulation*** in a device which is plasma treated (column 6, lines 32-40). The reference of Cusack does not particularly point out an agglutinating agent but it does suggest the use of one, wherein a region in the device is surface treated to provide for more efficient clotting (column 6, lines 32-40). However, the examiner provided a second reference to particularly address the agglutination reagent taught by Mintz. Mintz teaches an apparatus and method for analyzing the influence of ***coagulant and anticoagulant reagents*** in blood (see summary). Those reagents are listed in column 6, lines 54-59. Therefore, the examiner views the combination to Cusack in view of Mintz to be proper.

3. Applicant argument that the claimed invention is based on determining the strength of an agglutination reaction that is determined by the amount of light absorbed or scattered and that the prior art of Cusack teaches agglutination measurements by fluid flow rates is noted but not found to be persuasive.

In response, the rate of agglutinating measurements by the rate of the blood flow appears to be encompasses by determining the strength of an agglutination action.

4. Applicant argues that the reference of Shepherd et al teaches the use of a predetermined wavelength to minimize the error criterion in absorbance and detecting the amount of scattered radiation to avoid any hemolysis interference, but Cusack et al use photodetectors to detect the presence of blood to start the timing cycle. Applicant's position is that the skilled artisan would have not

motivation to go to the added trouble of including a predetermined wavelength or detecting the amount of scattered radiation. These arguments are noted but not found to be persuasive.

In response, the examiner disagrees with applicant's assessment. The method of Shepherd can be performed to first to eliminate background noise by using a predetermined wavelength and followed up with the method of Cusack to detect the presence of blood and start the timing cycle for the agglutination procedure. One of ordinary skill in the art would always want to eliminate background noise to minimize the error criterion.

4. Applicant's argument that the instant invention can attain and determine blood type of the sample is noted but not found persuasive because these features are not taught in the instant claims.

5. Applicant argues that the methodology of Shepherd compensate for light scatter during the measurements is directed at the analysis of unaltered, whole blood in contrast to the instant claimed method that teaches light scatter during the measurements is directed at partially agglutinated samples. This argument is noted but not found to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

6. Applicant's argument that claim 22 is patentable over the combination of Cusack, Mintz, Shepherd and Zabetakis for reasons set forth above is noted but not found to be persuasive. Applicant further argues that Zabetakis provides no motivation to combine these teachings because Zabetakis teaches a means to achieve a homogenous mix of fluids rather than moving fluids in a fashion gentle enough to promote and detect agglutination reactions is also noted but not found to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With respect to new claim 30, the references in combination teach the use of whole blood samples and as applicant also pointed out in the reference of Shepherd (see page 9 of arguments).

Conclusion

7. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Davis Deborah can be reached on (571) 272-0818. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
Patent Examiner
May 11, 2006

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